

Claims

1. A medicament dispenser device for use in the delivery of a multi-component combination medicament product, the device comprising

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a first medicament container containing plural co-formulation compatible medicament components;

first release means for releasing the contents of the first medicament container for
10 delivery thereof;

at least one further medicament container, each containing at least one co-formulation incompatible medicament component; and

15 at least one further release means for releasing the contents of each at least one further medicament container for delivery thereof,

wherein the at least one co-formulation incompatible medicament component is kept separate from the plural co-formulation compatible components until the point of
20 release thereof for delivery in combination.

2. A medicament dispenser device according to claim 1, wherein the dispenser device comprises a first medicament container containing two co-formulation compatible medicament components and one further medicament container
25 containing one co-formulation incompatible medicament component.

3. A medicament dispenser device according to claim 1, wherein the dispenser device comprises a first medicament container containing two co-formulation compatible medicament components and one further medicament container
30 containing two co-formulation incompatible medicament components.

4. A medicament dispenser device according to claim 1, wherein the dispenser device comprises a first medicament container containing two co-formulation compatible medicament components a second medicament container containing one co-formulation incompatible medicament component and a third medicament
5 container containing one co-formulation incompatible medicament component.
5. A medicament dispenser device according to any of claims 1 to 4, wherein the first medicament container and the at least one further medicament container are suitable for use with a medicament dispenser selected from the group consisting of a
10 reservoir dry powder inhaler (RDPI), a multi-dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI).
6. A medicament dispenser device according to any of claims 1 to 5, wherein the
15 first and at least one further medicament container are of a similar type.
7. A medicament dispenser device according to any of claims 1 to 5, wherein the first and at least one further medicament container are of a different type.
- 20 8. A medicament dispenser device according to any of claims 1 to 7, wherein the first release means and the at least one further release means are coupled together
9. A medicament dispenser device according to any of claims 1 to 8, wherein the device further comprises a mixing chamber including a first inlet for receiving the
25 released contents of the first medicament container; a second inlet for receiving the released contents of the at least one further medicament container; and an outlet for delivery of combination medicament product therefrom.
10. A medicament dispenser device according to any of claims 1 to 9, wherein the
30 plural co-formulation compatible medicament components and the at least one co-formulation incompatible medicament component are selected from the group

consisting of anti-inflammatory agents, anticholinergic agents, other β_2 -adrenoreceptor agonists, anti-infective agents and antihistamines.

11. A medicament dispenser device according to claim 10, wherein said anti-inflammatory agents are selected from the group consisting of corticosteroids and NSAIDs.

12. A medicament dispenser device according to claim 11, wherein said corticosteroids are selected from the group consisting of methyl prednisolone, prednisolone, dexamethasone, fluticasone propionate, $6\alpha,9\alpha$ -difluoro- 17α -[(2-furanylcabonyl)oxy]- 11β -hydroxy- 16α -methyl-3-oxo-androsta-1,4-diene- 17β -carbothioic acid S-fluoromethyl ester, $6\alpha,9\alpha$ -difluoro- 11β -hydroxy- 16α -methyl-3-oxo- 17α -propionyloxy- androsta-1,4-diene- 17β -carbothioic acid S-(2-oxo-tetrahydrofuran-3S-yl) ester, beclomethasone esters, budesonide, flunisolide, mometasone esters, triamcinolone acetonide, rofleponide, ciclesonide, butixocort propionate, RPR-106541 and ST-126.

13. A medicament dispenser device according to claim 12, wherein said corticosteroids are selected from the group consisting of fluticasone propionate, $6\alpha,9\alpha$ -difluoro- 11β -hydroxy- 16α -methyl- 17α -[(4-methyl-1,3-thiazole-5-carbonyl)oxy]-3-oxo-androsta-1,4-diene- 17β -carbothioic acid S-fluoromethyl ester and $6\alpha,9\alpha$ -difluoro- 17α -[(2-furanylcabonyl)oxy]- 11β -hydroxy- 16α -methyl-3-oxo-androsta-1,4-diene- 17β -carbothioic acid S-fluoromethyl ester.

14. A medicament dispenser device according to any of claims 11 to 13, wherein said NSAIDs are selected from the group consisting of sodium cromoglycate, nedocromil sodium, phosphodiesterase (PDE) inhibitors, leukotriene antagonists, inhibitors of leukotriene synthesis, iNOS inhibitors, tryptase and elastase inhibitors, beta-2 integrin antagonists, adenosine receptor agonists or antagonists, cytokine antagonists and inhibitors of cytokine synthesis.

15. A medicament dispenser device according to claim 14, wherein said phosphodiesterase (PDE) inhibitors are selected from the group consisting of theophylline, PDE4 inhibitors and mixed PDE3/PDE4 inhibitors.

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16. A medicament dispenser device according to claim 10, wherein said other β_2 -adrenoreceptor agonists are selected from the group consisting of salmeterol, salbutamol, formoterol, fenoterol, terbutaline and any salts or solvates thereof.

10 17. A medicament dispenser device according to claim 10, wherein said anticholinergic agents are selected from the group consisting of M_1 , M_2 , M_1/M_2 and M_3 receptor antagonists.

18. A medicament dispenser device according to claim 17, wherein said
15 anticholinergic agents are selected from the group consisting of ipratropium, oxitropium, tiotropium and any salts or solvates thereof.

19. A medicament dispenser device according to any of claims 1 to 18, wherein the plural co-formulation compatible medicament components comprise a β_2 -
20 adrenoreceptor agonist and a corticosteroid; and the at least one further co-formulation incompatible medicament component is selected from the group consisting of a PDE-4 inhibitor, an anti-cholinergic, and any mixtures thereof.

20. A medicament dispenser device according to claim 19, wherein the β_2 -
25 adrenoreceptor agonists is selected from the group consisting of salbutamol, salmeterol, formoterol and any salts and solvates thereof; and the corticosteroid is selected from the group consisting of beclomethasone ester, a fluticasone ester, budesonide and any salts of solvates thereof.

30 21. A medicament dispenser device according to claim 20, wherein the plural co-formulation compatible medicament components comprise fluticasone propionate

and salmeterol xinafoate; and the co-formulation incompatible component is selected from the group consisting of a PDE-4 inhibitor, an anti-cholinergic, and any mixtures thereof.

5 22. A medicament dispenser device according to claim 20, wherein the plural co-formulation compatible medicament components comprise budesonide and formoterol fumarate; and the co-formulation incompatible component is selected from the group consisting of a PDE-4 inhibitor, an anti-cholinergic, and any mixtures thereof.

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23. A medicament pack for use with the medicament dispenser device according to any of claims 1 to 22, the pack comprising

a first medicament container containing plural co-formulation compatible medicament
15 components; and

at least one further medicament container, each at least one further medicament container containing at least one co-formulation incompatible medicament component; and

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wherein the at least one co-formulation incompatible medicament component is kept separate from the plural co-formulation compatible components.

24. A medicament pack according to claim 23; wherein the plural co-formulation
25 compatible medicament components and the at least one co-formulation incompatible medicament component are selected from the group consisting of anti-inflammatory agents, anticholinergic agents, other β_2 -adrenoreceptor agonists, anti-infective agents and antihistamines.

30 25. A medicament pack according to claim 24, wherein said anti-inflammatory agents are selected from the group consisting of corticosteroids and NSAIDs.

26. A medicament pack according to claim 25, wherein said corticosteroids are selected from the group consisting of methyl prednisolone, prednisolone, dexamethasone, fluticasone propionate, 6 α ,9 α -difluoro-17 α -[(2-furanylcarbonyl)oxy]-
5 11 β -hydroxy-16 α -methyl-3-oxo-androsta-1,4-diene-17 β -carbothioic acid S-fluoromethyl ester, 6 α ,9 α -difluoro-11 β -hydroxy-16 α -methyl-3-oxo-17 α -propionyloxy-androsta-1,4-diene-17 β -carbothioic acid S-(2-oxo-tetrahydro-furan-3S-yl) ester, beclomethasone esters, budesonide, flunisolide, mometasone esters, triamcinolone acetonide, rofleponide, ciclesonide, butixocort propionate, RPR-106541 and ST-126.

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27. A medicament pack according to claim 26, wherein said corticosteroids are selected from the group consisting of fluticasone propionate, 6 α ,9 α -difluoro-11 β -hydroxy-16 α -methyl-17 α -[(4-methyl-1,3-thiazole-5-carbonyl)oxy]-3-oxo-androsta-1,4-diene-17 β -carbothioic acid S-fluoromethyl ester and 6 α ,9 α -difluoro-17 α -[(2-
15 furanylcarbonyl)oxy]-11 β -hydroxy-16 α -methyl-3-oxo-androsta-1,4-diene-17 β -carbothioic acid S-fluoromethyl ester.

28. A medicament pack according to any of claims 25 to 27, wherein said NSAIDs are selected from the group consisting of sodium cromoglycate, nedocromil
20 sodium, phosphodiesterase (PDE) inhibitors, leukotriene antagonists, inhibitors of leukotriene synthesis, iNOS inhibitors, tryptase and elastase inhibitors, beta-2 integrin antagonists, adenosine receptor agonists or antagonists, cytokine antagonists and inhibitors of cytokine synthesis.

25 29. A medicament pack according to claim 28, wherein said phosphodiesterase (PDE) inhibitors are selected from the group consisting of theophylline, PDE4 inhibitors and mixed PDE3/PDE4 inhibitors.

30. A medicament pack according to claim 24, wherein said other β_2 -adrenoreceptor agonists are selected from the group consisting of salmeterol, salbutamol, formoterol, fenoterol, terbutaline and any salts or solvates thereof.

5 31. A medicament pack according to claim 24, wherein said anticholinergic agents are selected from the group consisting of M_1 , M_2 , M_1/M_2 and M_3 receptor antagonists.

32. A medicament pack according to claim 31, wherein said anticholinergic
10 agents are selected from the group consisting of ipratropium, oxitropium, tiotropium and any salts or solvates thereof.

33. A medicament pack according to any of claims 23 to 32, wherein the plural co-formulation compatible medicament components comprise a β_2 -adrenoreceptor
15 agonist and a corticosteroid; and the at least one further co-formulation incompatible medicament component is selected from the group consisting of a PDE-4 inhibitor, an anti-cholinergic, and any mixtures thereof.

34. A medicament dispenser device according to claim 33, wherein the β_2 -
20 adrenoreceptor agonist is selected from the group consisting of salbutamol, salmeterol, formoterol and any salts and solvates thereof; and the corticosteroid is selected from the group consisting of beclomethasone ester, a fluticasone ester, budesonide and any salts of solvates thereof.

25 35. A medicament dispenser device according to claim 34, wherein the plural co-formulation compatible medicament components comprise fluticasone propionate and salmeterol xinafoate; and the co-formulation incompatible component is selected from the group consisting of a PDE-4 inhibitor, an anti-cholinergic, and any mixtures thereof.

36. A medicament dispenser device according to claim 34, wherein the plural co-formulation compatible medicament components comprise budesonide and formoterol fumarate; and the co-formulation incompatible component is selected from the group consisting of a PDE-4 inhibitor, an anti-cholinergic, and any mixtures
5 thereof.

37. Refill medicament pack in kit of parts form for use with the medicament dispenser device according to any of claims 1 to 22, the refill pack comprising

10 as a first part of said kit, a first medicament container containing plural co-formulation compatible medicament components; and

as a further part of the kit, at least one further medicament container, each at least one further medicament container containing at least one co-formulation
15 incompatible medicament component; and

wherein the at least one co-formulation incompatible medicament component is kept separate from the plural co-formulation compatible components.